

OCT 14 2003

510(k) Summary

K033165

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-7637

Contact Person: Kerwin Kaufman

Date Prepared: September 26, 2003

2) Device name Proprietary name: Preciset DAT Amphetamine and Cfas DAT Qualitative Amphetamine Calibrators

Common name: Calibrators, Drug Specific

Classification name: Clinical Toxicology Calibrator

3) Predicate devices We claim substantial equivalence to the currently marketed Roche calibrators:
Abuscreen OnLine Preciset DAT I Calibrators, cleared in 510(k) K951595 (formerly Abuscreen OnLine Calibration Pack).

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4) Device Description

Roche Preciset DAT Amphetamine calibrators contain 6 levels of amphetamines, prepared by the quantitative addition of d-amphetamine to drug-free human urine. Drug concentrations are verified by GC/MS. The calibrator set contains six levels of amphetamines in bottles 1-6. Bottle 1 is negative (drug free) human urine, followed by bottles 2-6 containing increasing amounts of amphetamines. The respective target concentrations of amphetamines included is as follows:

Amphetamines: 0, 250, 500, 1000, 1500, 2000 ng/ml

Roche Cfas DAT Qualitative Amphetamine calibrators contain a single level of amphetamines at a target concentration of 1000 ng/ml, prepared by the quantitative addition of d-amphetamine to drug-free human urine. Drug concentrations are verified by GC/MS. The calibrator set contains 3 bottles of the single level amphetamines at 5 ml each.

5.) Intended Use

The Preciset DAT Amphetamine calibrators are designed for the calibration of the Roche Abuscreen OnLine assay for Amphetamines and the cassette COBAS Integra Amphetamines (AMPS) for the determination of amphetamines in human urine on automated clinical chemistry analyzers.

The Cfas DAT Qualitative Amphetamine calibrator is designed for the qualitative calibration of the Roche Abuscreen OnLine assay for Amphetamines and the cassette COBAS Integra Amphetamines (AMPS) for the determination of amphetamines in human urine on automated clinical chemistry analyzers.

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510(k) Summary, Continued

6.) Comparison to the Predicate Device

The Roche Preciset DAT Amphetamine and Cfas DAT Qualitative Amphetamine calibrators are substantially equivalent to other products cleared for commercial distribution intended for similar use. Most notably, they are substantially equivalent to the currently marketed Roche Abuscreen OnLine Preciset DAT I multianalyte calibrators, manufactured for Roche Diagnostics and cleared in 510(k) submission K951595 by Roche Diagnostics.

The Preciset DAT Amphetamine calibrators contain 6 levels of amphetamines, prepared by the quantitative addition of d-amphetamine to drug-free human urine with added preservative. The Cfas DAT Qualitative Amphetamine calibrator contains a single level of amphetamines, prepared by the quantitative addition of d-amphetamine to drug-free human urine with added preservative.

The predicate device, Abuscreen OnLine Preciset DAT I calibrators contains a mixture of 9 different drugs, prepared by the quantitative addition of drug or drug metabolite to drug-free human urine with added preservatives and stabilizers. Drugs included are amphetamines, barbiturates, benzodiazepines, cocaine, methadone, methaqualone, opiates, phencyclidine, and propoxyphene. The calibrator set contains four levels for each drug.



DEPARTMENT OF HEALTH & HUMAN SERVICES

OCT 14 2003

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Kerwin Kaufman
Regulatory Affairs Consultant
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k033165
Trade/Device Name: Preciset DAT Amphetamine Calibrators and Cfes DAT Qualitative Amphetamine Calibrator
Regulation Number: 21 CFR 862.3200
Regulation Name: Clinical Toxicology Calibrator
Regulatory Class: Class II
Product Code: DLJ
Dated: September 26, 2003
Received: September 30, 2003

Dear Mr. Kaufman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

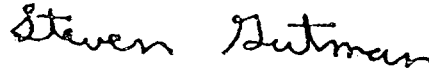
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k)
Number (if
known):

K03 3165

Device Name: **Preciset DAT Amphetamine Calibrators and
Cfas DAT Qualitative Amphetamine Calibrator**

Indications
for Use:

The Preciset DAT Amphetamine calibrators are designed for the calibration of the Roche Abuscreen OnLine assay for Amphetamines and the cassette COBAS Integra Amphetamines (AMPS) for the determination of amphetamines in human urine on automated clinical chemistry analyzers.

The Cfas DAT Qualitative Amphetamine calibrator is designed for the qualitative calibration of the Roche Abuscreen OnLine assay for Amphetamines and the cassette COBAS Integra Amphetamines (AMPS) for the determination of amphetamines in human urine on automated clinical chemistry analyzers.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR Over-the-Counter Use ☐
(Per 21 CFR 801.109)

(Optional format 1-2-96)

Carol C. Benson / Jean Cooper, DVM
Division Sign-Off

**Office of In Vitro Diagnostic Device
Evaluation and Safety**

510(k) K03 3165